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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,019	08/29/2003	Gregory R. Gingera	1213EC	9672

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/652,019		GINGERA ET AL	
	Examiner		Art Unit	
	David H. Kruse		1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-8,12-14,16-24,71 and 72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-8,12-14,16-24,71 and 72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/29/03&3/21/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-24, 71 and 72 in the reply filed on 21 March 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Specification

3. The disclosure is objected to because of the following informalities: The specification is objected to because of Figures in the specification at page 3, 11 and 12. See 37 CFR § 1.74. In addition, the specification does not contain a Brief Description of the Drawings. See 37 CFR § 1.84.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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5. Claims 1, 6-8, 12, 16 and 19-24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 12 and 16 are indefinite because it is unclear if the mutant AHAS1 and AHAS3 is responsible for the tolerance to a level of herbicide, hence the metes and bounds of the claims are unclear.

Claims 6-8 and 19-24 are also indefinite because they do not obviate the indefiniteness of the claim upon which they depend.

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-3, 6-8, 12-14, 16-24, 71 and 72 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a *Brassica juncea* plant and parts thereof tolerant to a level of herbicide that prevents or inhibits the growth of a wild type *Brassica juncea* plant, wherein the plant contains an AHAS1 and an AHAS3 mutation.

Applicant describes a method of making the claimed plant or parts thereof using *Brassica napus* variety 46A72 to cross with a *Brassica juncea* plant, followed by back-

crossing with the *B. juncea* species (page 9 of the specification). In addition, Applicant describes three *Brassica* lines with the *B. juncea* phenotype in lines 98SJ-23841, 98SJ-23844 and 98SJ-23845 (see page 10, 1st paragraph of the specification).

Applicant does not describe the genus of claimed plants or parts thereof. Neither does Applicant describe any related structural feature of the AHAS1 and AHAS3 mutant that produces the claimed function of herbicide tolerance.

Hence, it is unclear that Applicant was in possession of the invention as broadly claimed. See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. See *Vas-Cath Inc. v. Mahurkar* 1991 (CA FC) 19 USPQ2d 1111, 1115, which teaches that the purpose of the written description is for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or

different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.

8. Claims 1-3, 6-8, 12-14, 16-24, 71 and 72 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims a *Brassica juncea* plant and parts thereof tolerant to a level of herbicide that prevents or inhibits the growth of a wild type *Brassica juncea* plant, wherein the plant contains an AHAS1 and an AHAS3 mutation.

Applicant teaches a method of making the claimed plant or parts thereof using *Brassica napus* variety 46A72 to cross with a *Brassica juncea* plant, followed by back-crossing with the *B. juncea* species (page 9 of the specification). In addition, Applicant teaches three *Brassica* lines with the *B. juncea* phenotype in lines 98SJ-23841, 98SJ-23844 and 98SJ-23845 (see page 10, 1st paragraph of the specification).

Applicant does not teach the genus of claimed plants or parts thereof, or how to make such plants without undue trial and error experimentation.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of

working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant admits that there were unexpected difficulties encountered in the backcross-breeding program as a result of the linkage between the *B. napus* phenotype and the herbicide tolerant trait (page 10, 4th paragraph of the Specification). The art teaches that Gingera *et al.* (U.S. Pat. No. 6,613,963) disclose three *B. juncea* lines with tolerance to imidazolinone herbicides derived from an interspecific cross between *B. juncea* and a tolerant *B. napus* variety, followed by three back-crosses to *B. juncea*. It is disclosed that the plants were tolerant to herbicide applied at the usual field rate. No molecular information is provided regarding how many mutated *B. napus* genes were actually transferred and, if both mutated genes transferred, where they are located in the *B. juncea* genomes. Since *B. juncea* and *B. napus* share the A genome, it would presumably be simple to transfer the mutated AHAS3 gene located on the A genome. It will be much more difficult to transfer the mutant AHAS1 gene from the C genome of *B. napus* to the B genome of *B. juncea*. When backcrossing to *B. juncea*, there will be a tendency to have B genome chromosomes replace the C chromosomes and thus the mutated AHAS1 gene will be lost. Selection for herbicide tolerance was carried out at each stage, but according to Swanson *et al.* (Theor Appl Genet 78:525-530, 1989), the mutated AHAS3 gene on the A genome alone will provide tolerance to the usual field rate of herbicide. Thus, without the type of molecular information regarding the *B. juncea* AHAS gene sequences provided by the invention of Yao *et al.*, there would be no

way to confirm that the mutated AHAS1 gene from *B. napus* was successfully transferred to *B. juncea*. While the mutated AHAS1 and AHAS3 genes together will act additively to provide enhanced tolerance to imidazolinone herbicides (Swanson et al., Theor Appl Genet 78:525-530, 1989), this will not be apparent at the herbicide rate disclosed by Gingera et al. See Yao et al., United States Patent Application 2005/0283858, pages 1-2, ¶ 0008. Hence, given Applicant's limited guidance, the nature of the invention, the state of the prior art, the relative skill of those in the art, the unpredictability of the art, and the breadth of the claims, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to make and use the claimed plants.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR § 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR § 3.73(b).

10. Claims 1-3, 6-8, 12-14, 16-24, 71 and 72 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,613,963. Although the conflicting claims are not identical, they are not patentably distinct from each other because the *Brassica juncea* plant of the '963 patent renders obvious the genus of *Brassica juncea* plants of the instant claims.

Conclusion

11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER



David H. Kruse, Ph.D.
30 May 2006

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13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.